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EXAMINER	
PORTNER, VIRGINIA ALLEN	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/693,377	BOONE ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6-22,24 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-22,24 and 27* is/are rejected.

7)☒ Claim(s) *13-14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3,6-22, 24 and 27 are pending.
Claims 4-5,23, 25-26 and 28-29 have been canceled.
All claims recite a new combination of claim limitations.

Objections/Rejections Withdrawn

1. ***Claim Rejections - 35 USC § 112*** Claims 1-27 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement in light of the claim amendment defining the subject/patient population to exclude breast fed infants.

2. Withdrawn in light of claim amendments submitted: Claims 1-27 rejected under 35 USC 112, second paragraph: provides for the use of lactoferrin (see claim 1 "is present"; claims 2-3, 6-7, 23 "is used"; claims 4-6 "may be"; 8-10: "are measured" , "is measured" etc.), but, since the claims do not set forth any active, positive steps delimiting how this use is actually practiced.

3. Withdrawn in light of remarks and claim amendments submitted: Claims 17-19 and 20-22 recite method steps of adding antigens to the sample of claims 11 and 1, but the methods of detecting anti-Saccharomyces cerevisiae antibodies and anti-neutrophil cytoplasmic antibodies are optionally set forth in claims 1 and 11 by the recitation **"if so"**. The methods of claims 17-19 and 20-22 are optional methods steps to only be carried out when the lactoferrin level in the patient sample of claim 1 is positive, the samples of claims 17-22 are not defined to be positive, and therefore set forth a combination of claim limitations that are only optionally carried out. The recitation of additional optional methods steps does not further limit the optional method of claims 1 and 11. The recitation of "further comprises" additional optional methods steps, does not set forth positively recited methods steps for the claimed methods.

4. Withdrawn in light of claim amendments submitted: Claims 13-14 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 13-16 create a readable sample by contacting the treated sample with enzyme-linked polyclonal antibodies, but how the antibodies create the readable sample is not clearly nor distinctly claimed, in light of the critical and essential binding specificity of the polyclonal antibodies is not claimed. See In re Mayhew.

5. Withdrawn in light of claim amendments submitted: Claims 13-14, 18-19 and 21-22 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: forming antigen/antibody complexes specific to lactoferrin, Saccharomyces

cerevisiae antigens and neutrophil cytoplasmic antigens and removing any non-specific human immunoglobulin not contained in the specific antigen/antibody complexes, adding anti-human immunoglobulin antibodies labeled with an enzyme; adding enzyme substrate to produce a readable sample. The methods as now claimed detect any human immunoglobulin that is readable and fecal samples are known to contain a plurality of immunoglobulins that are not directed to lactoferrin, Saccharomyces cerevisiae antigens and neutrophil cytoplasmic antigens . The methods as now claimed are not directed to specifically detected only those antibodies or human immunoglobulins that are antigen specific for the antigens recited in claim 1.

6. Withdrawn in light of claim amendments submitted Claims 15-16 recite the limitation "purified lactoferrin" in dependence upon claims 1, 11-14. Claims 1, 11-14 do not recite any purification steps, and the only source of lactoferrin recited in the claims is the fecal sample of claim 1, which may or may not contain lactoferrin. There is insufficient antecedent basis for this limitation in the claim.

7. Withdrawn in light of claim amendments submitted Claim 24 rejected under 35 U.S.C. 102(b) as being anticipated by Martins et al (1995). Martins et al disclose a method that comprises the step of Obtaining a whole blood, saliva, sputum (mucosal secretion sample) and gingival swabs (bodily fluid) from a patient (see abstract);Determining whether lactoferrin is present in the sample (see abstract, negative for lactoferrin as an inflammatory marker in 7 individuals with healthy gums and teeth ; 4 edentulous patients were negative (see Figure 1 and 2, page 764). Martins et al anticipates the instantly claimed invention as now claimed.

Rejections Maintained/Response to Arguments

8. Applicant's arguments filed August 22, 2007 have been fully considered but they are not persuasive.

9. Rejection Maintained: The rejection of claims 13-14, 17-18 and 21-23 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements (presented in paragraph 9, page 4 of the Office Action dated mailed February 22, 2007) is traversed on the grounds that "Applicants have amended the claims to include these elements. As such, Applicants request withdrawal of these rejections"

10. It is the position of the examiner that none of the claims have been amended to recite polyvalent antibodies to human immunoglobulin labeled with horseradish peroxidase, and the claim amendments do not add any horseradish peroxidase labeled anti-human immunoglobulin antibodies to a diluted fecal sample that is readable at 450 nm . therefore this portion of the rejection of claims 13-14 and 21-22 is maintained for reasons of record.

11. While the examiner agrees claim 21 has been amended to recite the phrase "to create an enzyme-linked antibody bound sample", the polyvalent antibodies with which the sample is treated do not comprise an enzyme linked to them. Applicant's amendment of the claims have not defined/claimed the polyvalent antibodies to comprise a horseradish peroxidase conjugated enzyme, the enzyme being conjugated to the polyvalent antibodies. Therefore it is the position of the examiner that the polyclonal antibodies of claims 21-22 do not comprise an enzyme and these claims have not been so amended to comprise an enzyme that is readable in the treated sample. The claims are still incomplete by omitting a linked enzyme essential for producing a readable sample. Additionally, claim 22 determines an optical density at 450 nm, but no reagents or components in the diluted fecal sample are positively recited as comprising an emission spectra of 450 nm. What components in the fecal sample are readable at 450 nm? An essential element is missing form the claims that would be readable at 450 nm. See In re Mayhew.

12. ***Maintained,Claim Rejections - 35 USC § 102*** Claims 1,8-12, 13, 24 rejected under 35 U.S.C. 102(b) as being anticipated by Guerrant et al (US Pat. 5,124,252) is traversed on the grounds that "Applicant have amended claims 1 and 24 such that the steps of determining whether a fecal sample contains elevated levels of ASCA and ANCA are not optional.

13. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., measuring lactoferrin, ASCA and ANCA in all samples, whether lactoferrin is negative or not) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

14. Claims 1 and 24 while amended, only carries out the determining steps for ASCA and ANCA when the lactoferrin determination is POSITIVE and ELEVATED. Guerrant et al was applied against the claims for when the patient sample is negative or presents with unelevated lactoferrin levels. When the samples are negative, the additional tests are not required by the claims. With respect to claim 24, when the lactoferrin level is not elevated, Guerrant et al determines that the patient has non-inflammatory diarrhea, a symptom of irritable bowel syndrome. While Guerrant et al (see preamble of allowed claims) does not refer to non-inflammaotry diarrhea as irritable bowel syndrome, a patient that presents with diarrhea and does not have elevated levels of lactoferrin, would not have inflammatory bowel disease, and would be a patient with irritable bowel. Therefore Guerrant et al still anticipates the instantly claimed invention as now claimed, for reasons of record and responses set forth herein.

15. Maintained, Claims 1-3,11-12 and 24, 27 rejected under 35 U.S.C. 102(b) as being anticipated by Fine et al (AJG, 1998) is traversed on the grounds that the "steps of determining whether a fecal sample contains elevated levels of ASCA and ANCA are not optional".

16. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., measurement of lactoferrin, ASCA and ANCA in all sample) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

It is the position of the examiner that ASCA and ANCA are only measured when the lactoferrin levels are elevated. Therefore, carrying out measurements for ASCA, and ANCA are not required when the level of lactoferrin is not elevated, say when the patient has irritable bowel syndrome that presents with unelevated levels of lactoferrin. In light of this fact, the ASCA and ANCA assays are optional for patients with irritable bowel syndrome and all samples are not measured for all three markers. The claims still read on samples from patient with unelevated levels of lactoferrin, such as samples from patients with irritable bowel syndrome or normal control samples, and are therefore still anticipated by Fine et al for reasons of record and responses set forth herein.

Instant claim 1-3 and 24-27: Fine et al disclose the instantly claimed invention directed to a method, the method comprising the steps of:

17. obtaining a fecal sample from a person (see page 1301, col. 2, first two paragraphs);

18. determining whether lactoferrin is present in the sample (see page 1302, Table 1 "Diagnoses in 92 Patients with a negative fecal lactoferrin Test", one patients test changed levels upon repeating the lactoferrin determination (see page 1302, Table 1, bottom of ledger narrative). The lactoferrin data was used to distinguish the patients that have inflammatory bowl disease or syndrome from those patients that have another bowl condition (see page 1302, Table 1).

Instant claim 11:further comprising diluting the sample (see page 1301, col. 2, paragraph 3).

Instant claim 12: further comprising contacting the sample with immobilized polyclonal antibodies latex beads were coated with rabbit anti-human lactoferrin, the endogenous lactoferrin is detected with the immobilized polyclonal antibodies. While the reference is silent with respect to whether the rabbit antibodies are polyclonal or monoclonal antibodies, it is clear that the reference does not discuss nor describe the production of hybridoma cell lines and monoclonal antibody production, therefore the antibodies are present in conventional rabbit sera that comprise polyclonal antibodies.

Fine et al anticipates the instantly claimed invention that does not require the claimed method to measure anything more than endogenous lactoferrin when the sample when the lactoferrin determination is considered negative in light of all the claims reciting the phrase "if so", which makes the following methods steps optional. Fine et al anticipates the instantly claimed invention as now claimed.

19. ***Maintained, Claim Rejections - 35 USC § 103*** Claims 1-3,6-10, 24 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al (2000) in view of Targan et al (1995) and Fine (PG-Pub 2001/0036639A1, filing date March 2, 2001) is traversed on the grounds that Nielsen et al does not determine ANCA in a fecal sample, the sample of Targen is a serum sample and Fine does not teach elevated levels of ANCA or ASCA in a fecal sample.

20. It is the position of the examiner that Nielsen et al teaches the measurement of lactoferrin, ANCA and ASCA in biological samples.

21. Lactoferrin is defined as a fecal marker for inflammatory bowel disease (see page 360, col. 2, lines 3-5).

22. Nielsen et al additionally teaches the importance of distinguishing between inflammatory bowel disease patients, specifically distinguishing between ulcerative colitis (UC) and Crohn's disease (CD)(see page 359, col. 2, middle of second paragraph).

23. Nielsen et al goes on to teach that pANCA is more common in UC than CD (see page 361, col. 2, paragraph 1) and that ASCA, antibodies to Saccharomyces cerevisiae, also known as

bakers yeast, is a marker for Crohn's disease (see page 361, col. 2, paragraph 2). Nielsen et al teaches the combined measurement (see page 361, col. 2, p. 3) of both ANCA and ASCA in order to gain insight into subclassification of inflammatory bowel disease patients.

24. Therefore, Nielsen et al clearly teaches measuring all three markers for assessment of disease activity in inflammatory bowel disease patients. The examiner agrees Nielsen et al is not applicable to the claims under 35 USC 102, but was applied against the claims under 35 USC 103, in view of guidance and teaching provided by Targan and Fine .

25. Applicant states that Targan et al analyze serum samples.

26. It is the position of the examiner that while Targan et al states ANCA is found in serum of ulcerative colitis patients, the reference focuses on measuring ANCA antibodies produced by B-cells in the colonic mucosa (see page 3262, col. 2, last sentence). The purpose of Targan et al's study is defined in col. 1, paragraph 1, on page 3263 where Targan et al found pANCA expressing cells in the mucosa of intestinal tissue (see also patient population, sample were obtained from intestinal tissue, page 3263, col. 1, paragraph 2). Figure 1 and Table 1 on page 3264 show patients with diverticulitis (non-IBD) and Crohn's disease to not significantly produce ANCA antibodies, while ANCA antibodies are significantly produced in UC patients . On page 3265, Discussion section, Targan et al state that "This study demonstrate the presence of ANCA-secreting B-cells within the mucosal LPL fraction from 70% of patients with UC." Targan et al site two additional studies that support their finding that "the intestinal mucosa may be a unique source of autoantibody producing B-cells". One of these results "indicates that B cells may be directly activated in the mucosal compartment by enteric Ags, and suggests that the

presence of Ab in serum is due to spill over of that production. Therefore, antibodies in fecal samples would not only come from the serum, but from B cells producing antibodies in the mucosal compartment of the intestine (see page 3265, col. 2, middle and end of first paragraph). Targan et al in summarizing their work states that their study indicated that "pANCA are being produced by local B cell populations within the lamina propria and are limited to mucosal tissues from UC patients", as well as states "Under appropriate conditions that result in chronic inflammation, such as are found in ileal pouches (ie., bacterial overgrowth and/or fecal stasis), these B cells are triggered to express pANCA.(page 3266, col. 2, first paragraph)" Therefore, Targan et al clearly teach the intestinal B cells to be the source of serum antibodies, the intestinal B cells expressing pANCA are associated with fecal material into which they would express pANCA antibodies. The person of ordinary skill in the art would have been motivated and had a reasonable expectation of success of measuring pANCA antibodies in a fecal sample from a patient with UC as Targan et al teach 70% of UC patient produce pANCA antibodies from B cells from an intestinal sample.

27. With respect to differential diagnosis of irritable bowel syndrome and inflammatory bowel disease, Fine et al teaches the essential criteria for differentiating these two conditions. Additionally, Fine et al still teaches the detections, measurement of ASCA antibodies from bakers' yeast which is also taught by Nielsen et al to be the source of these auto antibodies, the yeast being Saccharomyces cervevisiae (see Nielsen page 381, col. 2,p. 2). Clearly Nielsen et al and Fine et al are analogous art, and Fine et al teaches the presence of ASCA antibodies can be

measured/determined in fecal samples. The rejection of the claims is maintained for reasons of record and responses set forth herein.

Nielson et al describe biological activity markers of Inflammatory Bowel Disease (see title, page 359), wherein the markers include fecal lactoferrin (see page 360, col. 2, paragraph 1), and auto antibodies known as ANCA and ASCA (see page 361, col. 1-2). Nielson et al teach the methods step of :

Obtaining a fecal sample from a patient and determining the presence of fecal lactoferrin (see page 360, col. 2, paragraph 1) in order to provide for both sensitive and bowel-specific markers of disease, and further determining the presence or absence of ASCA and ANCA in the patient (see page 361, col. 1-2).

Nielson et al teach the importance of assessing disease activity in inflammatory bowel disease (IBD), to include ulcerative colitis and Crohn's disease based upon clinical parameters and various biological disease markers (see page 359, col. 1, abstract, first sentence), but differs from the instantly claimed invention by failing to determine ANCA and ASCA in the fecal sample.

Targan et al (1995) teach ANCA antibodies are presenting mucosal lesions of the bowel (whole abstract; and page 3266, col. 2, paragraph 1) in ulcerative colitis patients (non-serum samples, see table II, page 3265; p3264, Figure 1, Table 1; diluted 1:2 (see page 3264, Results section, first paragraph) in an analogous art for the purpose of quantitatively (see Table 1, page 3264, col. 5) defining pANCA production is a consequence of a mucosal immune response associated with ulcerative colitis (full last sentence of abstract; Fig. 1, p 3264). Fine et al (20010036639) teach a method of measuring fecal antibodies

directed to Saccharomyces cervesiae (ASCA) (see claims 1, 19-21 and 43; [0054]) in an analogous art for the purpose of determining the presence of antibodies associated with diseases or disorders of the bowel, to include diagnosis of irritable bowel syndrome (see page 3, [0020] and [0015; 0018, entire paragraph, as well as second half of paragraph. "diarrhea"]).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to measure fecal lactoferrin, ANCA and ASCA in a patient fecal sample because Nielson et al teach biological markers associated with inflammatory bowel disease, and teach fecal lactoferrin, as well as ANCA and ASCA to provide insight into disease activity associated with inflammatory bowel disease (see Nielsen et al, abstract, page 360, col. 2, p.1 and page 361, col. 1-2) and Targan et al and Fine et al teach the presence of ANCA and ASCA markers, respectively, are present in fecal/mucosal bowel samples and could be measured in the patient fecal sample along with the fecal lactoferrin determination. The person of ordinary skill in the art would have been motivated to determine fecal lactoferrin, along with fecal ANCA and ASCA markers because Nielsen et al teach that the lactoferrin is a measure of active bowel disease and measurement of ANCA and ASCA provide for differential diagnosis of the patient's type of inflammatory bowel disease (see Nielsen et al, page 361, col. 2, paragraph 3).

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of determining the presence or absence of inflammatory bowel disease (see page 360, col. 1, p. 1) by determining the fecal lactoferrin test, a marker for active bowel inflammatory disease, as taught by Nielsen et al, and if positive, further determining the presence and amount of ANCA and ASCA antibodies in the fecal sample because Nielsen et al teach that the "combined measurement of pANCA and ASCA

may be used advantageously in the sub-classification of IBD patients with indeterminate colitis. Both antibody specificities are measured by traditional quantitative solid phase immunosorbent assays, and they are highly specific (>90%) for both UC and CD with disease sensitivity around 50% in both cases (see Nielsen et al, page 361, col. 2, paragraph 3)."

Nielsen et al in view of Targen et al and Fine et al obviate the instantly claimed invention as now claimed.

New Claim Limitations/New Grounds of Rejection

Claim Objections

28. Claims 13 and 14 is objected to because of the following informalities: Claim 13 has been amended to recite the phrase "such that the enzyme-linked polyclonal antibodies are allowed to bind to capture lactoferrin to create an enzyme linked antibody bound sample sample". The second occurrence of the term "sample" should be deleted. The polyclonal antibodies of claim 13 and polyclonal antibodies of claim 12 are one and the same antibodies or different antibodies? This is not clearly set forth in the claims. The term "capture" need to be in the past tense ----captured-------.

29. Claim 14 recites the new term "bounds" and "ample"; this should be -----bound sample-------. Appropriate correction is required.

Claim Rejections - 35 USC § 112

30. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

31. Claims 1-3,6-22, 24 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. All of the claims have been amended to recite the phrase "other than a breast-fed infant"; this phrase does not evidence original descriptive support in the instant Specification and therefore constitutes New Matter. The instant Specification actually teaches obtaining samples from infants at "[0048] Fifty-six healthy subjects also were tested as controls. Twenty-eight of the subjects, or 50%, were male and twenty-eight of them, or 50%, were female. Ages of the subjects ranged from **infants** to 79 years. A summary of the tested subject population is illustrated in Table 9." No subpopulations within the infant population is described to be excluded from sampling and testing in the claimed methods. Claim 24 has been amended to recite the phrase "a person presenting with symptoms common to inflammatory bowel disease"; amendment of the other claims in the case and cancellation of the phrase "other than a breast-fed infant" could obviate this rejection.

32. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 depends from amended claim 1 and recites the phrase "capturing fragments"; what these fragments are is unclear in light of the fact what the fragments capture is not distinctly claimed, nor are the fragments defined in amended independent claim 1, from which claim 8 depends. What do the fragments capture?

33. The term "corresponds to the level" in claims 14, 19 and 22 recite a relative term which renders the claim indefinite. The term " corresponds to the level " is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. What the level corresponds to so the values can be interpreted is not distinctly claimed; something is missing for the sample to correspond to.

34. Claim 3 recites the limitation "diagnosis of irritable bowel syndrome" in dependence upon claims 2 and 1, respectively, but claim 1 recites "diagnosis of Crohn's disease" and "diagnosis of ulcerative colitis" and claim 2 recites the "diagnosis of inflammatory bowel disease". There is insufficient antecedent basis for this limitation in the claim because irritable bowel syndrome is not considered to be Crohn's disease, ulcerative colitis, and is distinguishable from irritable bowel syndrome. Therefore this phrase lacks antecedent basis in newly amended claims 1 and 2 which now recite specific diseases and not a syndrome.

35. Claim 23 recites the limitation "an enzyme linked antibody bound" in dependence upon claims 20, 11 and 1, but none of the claims from which claim 23 depends provides an enzyme linked antibody. Where the enzyme linked antibody comes from is not claimed. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

36. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

37. Claims 1, 3, 11-16 and 24 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 2004/0033537 (10/629,975). Although the conflicting claims are not identical, they are not patentably distinct from each other because The copending species of invention recites additional methods steps, but still utilizes a fecal sample to differentiate patients with irritable bowel syndrome from patients with IBD based upon endogenous lactoferrin levels. The copending species anticipates the instantly claimed genus of methods.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

38. Claims 1, 3, 11,12-13 14-16 and 24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 7,192,724. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed species anticipates the instantly claimed genus by measuring lactoferrin in a fecal sample and when the levels are not elevated, diagnosing IBS.

39. Claims 1-2, 3, 6-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 7-14 of copending Application No. PG-pub 2004,0126898 (10/656,034). Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending species anticipates the instantly claimed genus of methods, wherein the instant claims do not require the measurement of specific type of immunoglobulin antibodies as claimed in copending claim 13 that measures IgG, IgE, IgM, IgD, IgAsec, IgA.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

40. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell(acting SPE) can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vgp
October 26, 2007

MARK NAVARRO
PRIMARY EXAMINER